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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,998	10/08/2003	Rudi Beyaert	2676-4554.1US	7433
24247	7590	05/30/2006	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			ROOKE, AGNES BEATA	
			ART UNIT	PAPER NUMBER
			1653	
DATE MAILED: 05/30/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/680,998	Applicant(s) BEYAERT ET AL.	
	Examiner Agnes B. Rooke	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>12/04/03; 10/08/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to the paper filed on 04/27/2006. The Applicants elected without traverse claims 1-9 of Group II, where SEQ ID NO:9 is used.

Applicants added a new claim 18.

Thus, claims 1-18 are pending.

Claims 1-9 and 18 are currently under examination.

Upon revision of the restriction requirement, examiner realized that claims 8 and 9 are directed the different invention than invention in claims 1-7 of the application. However, in order to expedite the prosecution of the application examiner will prosecute claims 8 and 9, as currently included in the restriction requirement in Group II. Therefore, the restriction requirement is FINAL.

Claims 10-17 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions.

This application is a DIV of 09/702,953 filed on 10/31/2000 now patent 6,673,89, which is a CON of PCT/BE99/00055 filed on 05/05/1999.

Objection to Specification

The priority data must be updated in the first paragraph of the specification.

Objection to Claims

In claim 3, the Applicant must delete the non-elected subject matter (SEQ ID NOs:2, 5, and 19).

The full spelling of "ABIN" must be provided in claim 8.

The full spelling of "TNF" must be provided in claim 9.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-9 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, the phrase "A20 interacting proteins" is indefinite, since there can many potential known or unknown proteins that can interact with A20. Therefore, the claim is indefinite.

In claim 1, the A20 interacting protein must be included in the steps of the method claimed, otherwise the method is incomplete.

Claim 1 refers a method of screening a compound for its ability to interact with A20 interacting proteins. This claim is indefinite because it is unclear whether the word interact refers to increase in binding, decrease in binding or not binding at all of a compound with A20 interacting proteins? Therefore, further clarification in the claim is required.

In claims 1 and 2, the phrase "a protein of an NF- κ B related pathway" is indefinite, because it is unascertainable what particular protein is at issue.

In claims 1-6 and 18, the phrase "NF- κ B related pathway" is indefinite because it is not clear what particular biochemical pathway is at issue. Therefore, the claim is indefinite.

Claims 7-9 are included in the rejection because they depend from rejected claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claims 1, 2 and 18, there is no correlation between the structure of the proteins claimed and their function. For example, in claim 1, "A20 interacting proteins" do not have any structure provided in the method claimed; and in claims 1-6 and 18, the structure of "a protein of an NF- κ B related pathway" is also not provided, and thus a structure of a protein does not correspond with its function.

The court of Appeals for the Federal Circuit has recently held that such a general definition does not meet the requirements of 35 U.S.C. 112, first paragraph. "A written description of an invention involving chemical genus, like a description of a chemical

species, requires a precise definition, such as be structure, formula {or} chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 1997 U.S. App. LEXIS 18221, at *23, quoting *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). The court held that " in claims involving chemical materials, generic formulae usually indicate with specificity what generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. In claims to genetic material, however, a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish it from others. One skilled in the art therefore cannot, as one can do with a fully described genus visualize the identity of the members of the genus".

Here, the structure of the A20 binding proteins or the structure of a protein of an NF- κ B related pathway is not disclosed, therefore the written description requirement is not satisfied.

Scope of Enablement Rejection

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method that uses ABIN and ABIN2 (SEQ ID NO:9), it does not reasonably provide enablement for a method of screening a compound for its ability to interact with all possible A20 interacting proteins comprising a compound to be screened with a protein of an NF- κ B related pathway. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) eight factors should be addressed in determining enablement.

1.) The nature of the invention: the invention refers to a method of screening a compound for its ability to interact with A20 interacting proteins where a protein of an NF- κ B related pathway is used.

2.) The breadth of the claims: the claims are very broad because they refer to any possible A20 interacting proteins and any possible protein of an NF- κ B related pathway.

3.) The predictability or unpredictability of the art: the art is unpredictable because the potential possible A20 interacting proteins are not disclosed in the claims and an example of a protein of an NF- κ B related pathway is also not disclosed. Therefore, the art is unpredictable because it would be an undue burden on examiner to essay all potential candidates for the A20 interacting proteins and proteins of an NF- κ B related pathway.

4.) & 5.) The amount of direction or guidance presented: The specification on page 22, [0095] describes only two proteins that can interact with A20 protein : ABIN and ABIN2. It states that by comparing ABIN2 with ABIN, one can define two homologous regions and derive two consensus sequences: SEQ ID NO:8 and SEQ ID NO:9 that may be important for the interaction of these proteins with A20 and/or for their

further function in signal transduction. No other proteins, except ABIN or ABIN2 are described in the examples. Further, there are no specific examples in the experimentation data referring to proteins of an NF- κ B related pathway.

6.) The quantity of experimentation necessary: there is a large experimentation necessary to determine all possible A20 interacting proteins that are used in the method; and also potential proteins of an NF- κ B related pathway, since the plethora of choices is limitless, and there undefined.

7.) The state of the prior art: ABIN2 is known in the art as a protein that is A20-binding inhibitor of NF- κ B activation, for example.

8.) Level of skill in the art: the level of skill in this art is high with few years experience in the laboratory.

In consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teaching, and guidance presented. Absent factual data to the contrary, the amount and level of experimentation needed is undue, and the applicants are only enabled for ABIN and ABIN2 proteins that are used in the method claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 2 rejected under 35 U.S.C. 102(b) as being anticipated by Song et al., The tumor necrosis factor-inducible zinc finger protein A20 interacts with TRAF1/TRAF2 and inhibits NF- κ B activation, Proc. Natl. Acad. Sci. USA, vol. 93, p. 6721-6725, June 1996.

Song et al. teach and show that TRAF1/TRAF2 complex interacts with A20 in order to shut off TNFR1, TNRF2 and CD40 activation of NF- κ B pathway (see Figure 5, page 6725) in a reporter gene assay, anticipating claims 1, 2, and 18.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 4, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Song et al., The tumor necrosis factor-inducible zinc finger protein A20 interacts with TRAF1/TRAF2 and inhibits NF- κ B activation, Proc. Natl. Acad. Sci. USA, vol. 93, p. 6721-6725, June 1996.

The teachings of Song et al. are disclosed above.

It would have been obvious to one skilled in the art at the time the invention was made to design SEQ ID NO:9 because in view of the teachings of Song et al. TRAF2

binds to A20, and thus by inherency must comprise SEQ ID NO:9, which is a consensus sequence. (See Figures 8 and 9 for example).

One of ordinary skill in the art would have been motivated to design SEQ ID NO:9 by site directed mutagenesis method, since by inherency it would have been obvious to deduce SEQ ID NO:9 from the known sequence of TRAF2 that binds to A20.

Prior art of interest and examiner's notes:

1. The Journal of Immunology, 1996, 156, p. 1166-1173; discusses that A20 functions as a negative regulator of TNF and IL-1, see Abstract.
2. Blood, (April 1) 1998, 91, no.7, p. 2249-2258; discusses interaction of TRAF-1 and TRAF-2 which play role in NF- κ B activation, see left column, middle paragraph on page 2256.
3. The Journal of Cell Biology, June 28, 1999, vol. 145, p. 1471-1482, teaches that via yeast two-hybrid screening it is shown that the effect of A20 is mediated by its interaction with this NF- κ B inhibiting protein, ABIN. This publication is relevant to claims 8 and 9 of the instant invention.

Conclusion

The USPTO search engine GenCore version 5.1.7 found other sequences in the prior art that have 87.7 % identity to the SEQ ID NO:9 of the instant invention.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-

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2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

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